



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Sommadossi, et al.

Confirmation No.:

8101

Serial No.:

10/607,909

Art Unit:

1623

Filed:

June 27, 2003

Examiner:

Travis C. McIntosh III

For:

2'-C-METHYL-3'-O-L-VALINE

Attorney Docket No.: 11874-026-999

ESTER RIBOFURANOSYL

CYTIDINE FOR TREATMENT OF FLAVIVIRIDAE INFECTIONS

(417451-999026)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56

Mail Stop Amendment **Commissioner for Patents** P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and §1.97 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to the references listed on the attached List of References Cited by Applicant.

A copies of References B01 to B23 and C01 to C32 are submitted herewith. References A01 to A97 are U.S. patents and U.S. published applications. Therefore, copies of these references are not submitted herewith, pursuant to 37 C.F.R. § 1.98(a)(2)(ii).

Applicants respectfully request that the Examiner review the listed references and that the references be made of record in the file history of the application. Identification of references listed on PTO Form 1449 is not to be construed as an admission of Applicants or attorneys for Applicants that such references are available as "prior art" against the subject application.

Respectfully submitted,

Date:

April 18, 2007

Mark D. Kafka

for:

Reg. No. 59,569

04/20/2007 WABDELR1 00000057 10607909

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LIST CEREBERENCES CITED BY APPLICANT

(Use several sheets if necessary)

		Sheet 1 01 0			
	ATTY. DOCKET NO.	APPLICATION NO.			
	11874-026-999	10/607,909			
APPLICANT					
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	June 27, 2003	1623			

*Examiner			Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where Relevant Passages or Relevant Figure
Initials	A01	Document Number 3,116,282	mm/dd/yy 12/31/63	of Cited Document Hunter	Appear
· · · · · · · · · · · · · · · · · · ·	A02	3,891,623	6/24/75	Vorbruggen, et al.	
	A03	3,480,613	11/25/69	Walton, et al.	
	A04	4,209,613	6/24/80	Vorbruggen, et al.	
	A05	4,294,766	10/13/81	Schmidt, et al.	
-	A06	4,689,404	8/25/87	Kawada, et al.	
	A07	4,754,026	6/28/88	Kawada, et al.	
-	A08	4,814,477	3/21/89	Wijnberg, et al.	
	A09	4,952,740	8/28/90	Juge, et al.	
	A10	5,200,514	4/06/93	Chu	
	All	5,322,955	6/21/94	Matsumoto, et al.	
	A12	5,372,808	12/13/94	Blatt, et al.	
	A13	5,391,769	2/21/95	Matsumoto, et al.	
	A14	5,676,942	10/14/97	Testa, et al.	
	A15	5,696,277	12/9/97	Hostetler, at al.	
	A16	5,738,845	4/14/98	Imakawa	
	A17	5,750,676	5/12/98	Vorbruggen, et al.	
	A18	5,763,418	6/9/98	Matsuda, et al.	
	A19	5,780,617	5/31/94	Van Den Bosch, et al.	
	A20	5,789,608	8/4/98	Glazier	-
	A21	5,830,455	11/3/98	Valtuena, et al.	
	A22	5,849,696	12/15/98	Chretien, et al.	
	A23	5,908,621	6/1/99	Glue, et al.	
	A24	5,928,636	7/27/99	Alber, et al.	
	A25	5,942,223	8/24/99	Bazer, et al.	
	A26	5,977,061	11/2/99	De Clerq	
	A27	5,980,884	11/9/99	Blatt, et al.	
	A28	6,002,029	12/14/99	Hostetler, et al.	
	A29	6,063,628	5/16/00	Loeb, et al.	

LAI-2865957v1

EXAMINER

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LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT		
	Sommadossi, et al.		
-	FILING DATE	ART UNIT	
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U.S. PATENT DOCUMENTS Pages, Columns, Lines, Where *Examiner Date Name of Patentee or Applicant Relevant Passages or Relevant Figures mm/dd/yy Initials **Document Number** of Cited Document Appear A30 6,140,310 10/31/00 Glazier A31 6,153,594 11/28/00 Borretzen, et al. A32 6,172,046 1/09/01 Albrecht A33 6,248,878 6/19/01 Matulic-Adamic, et al. A34 6,252,060 6/26/01 Hostetler, et al. 6,271,212 8/07/01 Chu, et al. A35 6,277,830 8/21/01 Ganguly A36 6,340,690 1/22/02 A37 Bachand, et al. A38 6,369,040 4/09/02 Acevedo, et al. A39 6,395,716 5/28/02 Gosselin, et al. 6,436,437 8/20/02 Yatvin, et al. A40 9/3/02 A41 6,444,652 Gosselin, et al. 6,448,392 9/10/02 Hostetler, et al. A42 A43 6,455,508 9/24/02 Ramasamy, et al. A44 6,472,373 10/29/02 Albrecht 6,566,344 5/20/03 A45 Gosselin, et al. 6,566,365 5/20/03 Storer, et al. A46 A47 6,569,837 5/27/03 Gosselin, et al 6,599,887 7/29/03 Hostetler, et al. A48 6,605,614 8/12/03 Bachand, et al. A49 A50 6,748,161 6/8/04 Ko, et al. A51 6,752,981 6/22/04 Erion, et al. A52 6,777,395 8/17/04 Bhat, et al. A53 6,784,161 8/31/04 Ismaili, et al. 9/7/04 A54 6,787,526 Bryant, et al. A55 6,815,542 11/9/04 Hong, et al. 6,831,069 12/14/05 A56 Tam, et al. A57 6,875,751 4/05/05 Imbach, et al. A58 6,908,924 6/21/05 Watanabe, et al.

LAI-2865957v1

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	APPLICANT	
	Sommadossi, et al.	
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	June 27, 2003	1623

*Examiner		Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A59	6,911,424	6/28/05	Schinazi, et al.	прреш
	A60	6,946,450	9/20/05	Gosselin, et al.	
	A61	6,965,066	11/15/05	Jiang, et al.	
·····	A62	7,056,895	6/6/06	Ramasamy, et al.	
_	A63	2002/0019363	2/14/02	Ismaili, et al.	
÷	A64	2002/0052345	5/2/02	Schinazi, et al.	
	A65	2002/0055473	5/09/02	Ganguly, et al.	
	A66	2002/0055483	5/09/02	Watanabe, et al.	
	A67	2002/0099072	7/25/02	Bachand, et al.	
·· · · · ·	A68	2002/0127203	9/12/02	Albrecht	
	A69	2002/0147160	10/10/02	Bhat, et al.	
	A70	2002/0173490	11/21/02	Jiang, et al.	
	A71	2003/0028013	2/6/03	Wang, et al.	
	A72	2003/0039630	2/27/03	Albrecht	
	A73	2003/0050229	3/13/03	Sommadossi, et al.	
	A74	2003/0055013	3/20/03	Brass	
	A75	2003/0053986	3/20/03	Zahm	
	A76	2003/0083306	5/01/03	Imbach, et al.	
	A77	2003/0083307	5/1/03	Devos, et al.	
	A78	2003/0087873	5/08/03	Stuyver, et al.	
	A79	2004/0110717	6/10/04	Carroll, et al.	
	A80	2003/0124512	7/03/03	Styuver	
	A81	2003/0225028	12/4/03	Gosselin, et al.	
	A82	2003/0225037	12/4/03	Storer, et al.	
	A83	2003/0236216	12/25/03	Devos, et al.	
	A84	2004/0063622	4/1/04	LaColla, et al.	
	A85	2004/0077587	4/22/04	Sommadossi, et al.	
	A86	2004/0097462	5/20/04	Sommadossi, et al.	
	A87	2004/0102414	5/27/04	Sommadossi, et al.	

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(Use several sheets if necessary)	Sommadossi, et al.		
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*Examiner Initials		Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figure Appear
	A88	2004/0110718	6/10/04	Devos, et al.	
	A89	2004/0248844	12/9/04	Ismaili, et al.	
•	A90	2004/0266723	12/30/04	Otto, et al.	
	A91	2005/0020825	1/27/05	Storer, et al.	
_	A92	2005/0031588	2/10/05	Sommadossi, et al.	
· · · · · · · · · · · · · · · · · · ·	A93	2005/0090463	4/28/05	Roberts, et al.	
	A94	2005/0101550	5/12/05	Roberts, et al.	
	A95	2005/0107312	5/19/05	Keicher, et al.	
	A96	2005/0113330	5/26/05	Imbach, et al.	
	A97	2005/0124532	6/9/05	Sommadossi, et al.	

*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т
	B01	FR 1,581,628	9/19/69	Merck & Co. Inc.		
	B02	FR 2,662,165	11/22/91	Univ. Pier et Curie		
the Control of the Co	B03	JP 63215694	9/8/88	Yamasa Shoyu Co. Ltd.		
	B04	WO 94/01117	1/20/94	Koszalka, et al.	, to 1984 of the second	
	B05	WO 98/16184	4/23/98	ICN Pharmaceuticals		
	B06	WO 00/09531	2/24/00	Novirio Pharmaceuticals		
·*··	B07	WO 01/68663	9/20/01	ICN Pharmaceuticals		
	B08	WO 02/03997	1/17/02	ICN Pharmaceuticals		
	B09	WO 02/070533	9/12/02	Pharmasset		
	B10	WO 02/094289	11/28/02	F. Hoffmann-La Roche		
	B11	WO 02/100415	12/19/02	F. Hoffmann-La Roche		
	B12	WO 03/026589	4/3/03	Idenix Pharma.; CNRS; U. Montp.		
	B13	WO 03/026675	4/3/03	Idenix Pharma.; CNRS; U. Montp.		
	B14	WO 03/063771	8/7/03	Pharmasset		
	B15	WO 03/068162	8/21/03	Pharmasset		

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FOREIGN PATENT DOCUMENTS								
*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	B16	WO 03/068164	8/21/03	Pharmasset				
	B17	WO 03/072757	9/4/03	Biota Inc.				
•	B18	WO 03/093290	11/13/03	Genelabs Technologies				
	B19	WO 04/002422	1/8/04	Idenix Pharma.; Univ. D.S. Cagliari				
	B20	WO 04/002999	1/8/04	Idenix Pharma.; Univ. D.S. Cagliari				
	B21	WO 04/003000	1/8/04	Idenix Pharma.; Univ. D.S. Cagliari				
	B22	WO 04/028481	4/8/04	Genelabs Technologies				
	B23	WO 04/046159	6/3/04	F. Hoffmann-La Roche				

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	т
Tintiais	C01	Altman, et al., "TheSynthesis of I'-Methyl Carbocyclic Thymidine and Its Effect on Nucleic Acid Duplex Stability," Synlett, Thieme Verlag. Stuttgart, De, 10:853-855 (1994).	
	C02	Beigelman, et al., "Epimerization During the Acetolysis of 3-O-Acetyl-5-O-Benzoyl-1,2-o-Isopropylidene-3-C-Methyl-a, D-Ribofuranose. Synthesis of 3'-C-Methylnucleosides with the B-D-ribo-and a-D-arabino Configurations," Carbohydrate Research, 181:77-88 (1988).	
	C03	Carroll, S.S., et al., "Inhibition of hepatitis C virus RNA replication by 2'-modified nucleoside analogs," <i>J. Biol. Chem.</i> , 278(14): 11979-11984 (2003).	
	C04	Faivre-buet, et al., "Synthesis of Various 3'-Branched 2', 3'-Unsaturated Pyrimidine Nucleosides as Potential Anti-HIV Agents," Nucleotides & Nucleosides, 11(7): 1411-1424 (1992).	
	C05	Francesco, et al. Antiviral Research. 58: 1-16 (2003).	
	C06	Grouiller, et al., "Novel-p-toluensesulfaonylation and Thionocarbonylation of Unprotected Thymine Nucleosides," Synlett, 1993: 221-222 (1993).	
	C07	Haraguchi, et al., "Preparation and Reactions of 2'-and 3'- Vinyl Bromides of Uracil Nucleosides: Versatile Synthons for Anti-HIV Agents," Tetrahedron Letters, 32(28): 3391-94 (1991).	
	C08	Haraguchi, et al., "Stereoselective Synthesis of 1'-C-Branched Uracil Nucleosides from Uridine," Nucleotides & Nucleosides, 14(3-5): 417-420 (1995).	
	C09	Harry-O'Kuru, R.E., et al., "2'-C-alkylribonucleosides: Design, synthesis, and conformation," <i>Nucleosides & Nucleotides</i> , 16(7-9): 1457-60 (1997).	
	C10	Hattori, H., et al., "Nucleosides and nucleotides 175. Structural requirements of the sugar moiety for the antitumor activities of new nucleoside antimetabolites, 1-(3-C-ethynyl-b-D-ribo-pentofuranosyl)cytosine and – uracil," J. Med. Chem., 41: 2892-2902 (1998).	
	CH	Itoh, et al., "Divergent and Sterocontrolled Approach to the Synthesis of Uracil Nucleosides Branched at the Anomeric Position," J Org Chem, 60(3): 656-662 (1995).	
	C12	Kawana, et al, "The Deoxygenatio of Tosylated Adenosine Derivatives with Grignard Reagents," Nucleic Acids Symp Ser, 17:37-40 (1986).	
	C13	Lavaire, S., et al., "3'-deoxy-3'-C-trifluoromethyl nucleosides: Synthesis and antiviral evaluation," <i>Nucleosides &</i>	

EXAMINER

DATE CONSIDERED

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-	NON PATENT LITERATURE DOCUMENTS			
Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. Nucleotides, 17(12): 2267-2280 (1998).	Т	
	C14	Leyssen, P., et al., "Perspectives for the treatment of infections with Flaviviridae," Clinical Microbiology Reviews (Washington D.C.) 13(1): 67-82 (January 2000).		
•	C15	Martin, X., et al., "Intramolecular hydrogen bonding in primary hydroxyl of thymine 1-(1-deoxy-β-D-piscofuranosyl)nucleoside," <i>Tetrahedron</i> , 50(22): 6689-6694 (1994).		
	C16	Matsuda, A., et al., "Alkyl addition reaction of pyrimidine 2'-ketonucleosides: Synthesis of 2'-branched-sugar pyrimidine nucleosides (Nucleosides and Nucleotides LXXXI)," Chem. Pharm. Bull., 36(3): 945-953 (1988).		
•	C17	Matasuda, et al., "Nucelosides and Nucleotides 104. Radical and Palladium-Catalyzed Deoxygenation of the Allylic Alcohol Systems in the Sugar Moiety of Pyrimidine Nucelosides" Nucleotides & Nucleosides, 11(2-4): 197-226 (1992)		
	C18	Mikhailov, S.N., et al., "Substrate properties of C'-methylnucleoside and C'-methyl-2'-deoxynucleoside 5'-triphosphates in RNA and DNA synthesis reactions catalysed by RNA and DNA polymerases," <i>Nucleosides & Nucleotides</i> , 10(1-3): 339-343 (1991).		
	C19 -	Mikhailov, S.N., et al., "Hydrolysis of 2'- and 3'-C-methyluridine 2'c3'-cyclic monophosphates and interconversion and dephosphorlyation of the resulting 2'- and 3'-monophosphates: Comparison with the reactions of uridine monophophates," <i>J. Org. Chem.</i> , 57(15): 4122-4126 (1992).		
	C20	Oivanen, M., et al., "Additional evidence for the exceptional mechanism of the acid-catalyzed hydrolysis of 4-oxopyrimidine nucleosides: Hydrolysis of 1-(1-alkoxyalkyl)uracils, seconucleosides, 3'-C-alkyl nucleosides and nucleoside 3', 5'-cyclic monophosphates," <i>J. Chem. Soc. Perkin Trans.</i> 2, 1994: 309-314 (1994).		
	C21	Oral Session V, Hepatitis C Virus, Flaviviridae; 16 th International Conference on Antiviral Research (April 27, 2003, Savannah, Ga.) p A75-77.		
	C22	Samano, et al., "Synthesis and Radical-Induced Ring-Opening Reactions of 2'-Deoxyadenosine-2'- Spirocyclopropane and its Uridine analogue. Mechanistic Probe for Ribonucleotide Reductases," J Am Chem Soc, 114: 4007-08 (1992)		
	C23	Samano, et al., "Nucleic Acid Related Compounds. 7. 2',3'-Didehydro-2', 3'-Dideoxy-2' (and 3')-Methylnucleosides Via [3,3]-Sigmatropic Rearrangements of 2'(and 3')-Methylene-3'(and 2')-O-Thiocarbonyl Derivatives and Radical Reuction of a 2'-Chloro-3'Methylene Analogue," Can. J. Chem., 71: 186-191 (1993)		
	C24	Schmidt, C., et al., "The effects of 2'- and 3'-alkyl substituents on oligonucleotide hybridization and stability," Bioorg. & Med. Chem. Lett., 4(16): 1969-1974 (1994).		
	C25	Serafinowski, P.J., et al., "New method for the preparation of some 2'- and 3'-trifluoromethyl-2',3'-dideoxyuridine derivatives," <i>Tetrahedron</i> , 56(2):333-339 (1999).		
	C26	Tritsch, D., et al., "3'-β-ethynyl and 2'-deoxy-3'-β-ethynyl adenosines: First 3'-β-branched adenosine substrates of adenosine deaminase," <i>Bioorg. & Med. Chem. Lett.</i> , 10: 139-141 (2000).		
	C27	Tunitskaya, V.L., et al., "Substrate properties of C'-methyl UTP derivatives in T7 RNA polymerase reactions. Evidence for N-type NTP conformation," FEBS Letters, 400: 263-266 (1997).		
	C28	Vassiley, V., et al., "Bovine Viral Diarrhea Virus Induced Apoptosis Correlates with Increased Intracellular Viral RNA Accumulation." <i>Virus Research</i> , 69: 95-107 (2000).		
	C29	Walczak, K., et al., "Synthesis of 1-(3-alkyl-2,3-dideoxy-D-pentofuranosyl)uracils with potential anti-HIV activity," <i>Acta Chemica Scand.</i> , 45: 930-934 (1991).		
	C30	Walton, E., et al., "Branched-chain sugar nucleosides V. Synthesis and antiviral properties of several branched-chain sugar nucleosides," <i>J. Med. Chem.</i> , 12:306-309 (1969).		
	C31	Wolfe, M.S., et al., "A concise synthesis of 2'-C-methylribonucleosides," <i>Tetrahedron Letters</i> , 36(42): 7611-14 (1995).		
	C32	Wu, et al., "A New Stereospecific Synthesis of [3.1.0\ Bicyclic Cyclopropano Analog of 2'3'-Dideoxyuridine," Tetrahedron, 46(7): 2587-2592 (1990).		

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